3456. Misbranding of crude black molasses. U. S. v. Clinton D. Keagy and John S. Riley, Jr. Pleas of nolo contendere. Fine of $1,000 against each defendant, plus costs. (F. D. C. No. 30049. Sample Nos. 7789–K, 69196–K, 69375–K.)

INFORMATION FILED: February 13, 1951, Western District of Pennsylvania, against Clinton D. Keagy and John S. Riley, Jr., New Castle, Pa.

ALLEGED SHIPMENT: On or about November 23, 1949, by Clinton D. Keagy, from the State of Pennsylvania into the State of New York; and on or about May 22 and June 15, 1950, by Clinton D. Keagy and John S. Riley, Jr., from the State of Pennsylvania into the States of New York and Ohio.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a booklet entitled "Crude Black Molasses," which accompanied the article, were false and misleading. The statements represented that the article would be effective in the prevention and treatment of cancer, paralytic strokes, arthritis, ulcers, dermatitis eczema, psoriasis, high blood pressure, angina pectoris, weak heart, constipation, colitis, varicose veins, mental dullness, tuberculosis, infections, sinus trouble, pernicious anemia, anemia, bladder trouble, difficult urination, gallstones, nervousness, menopausal difficulties, erysipelas, pyorrhea, premature graying of the hair, and brittle and crumbling finger nails. The article would not be effective in the prevention and treatment of such diseases and conditions.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 21, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of $1,000, plus costs, against each defendant.

3457. Misbranding of Color-Therm device. U. S. v. 4 Devices, etc. Tried to the court. Order of dismissal. Reversed and remanded upon appeal (176 F. 2d 652). Decree of condemnation. Affirmed upon appeal (187 F. 2d 1005). (F. D. C. No. 26630. Sample Nos. 55166–K to 55168–K, incl.)

LIBEL FILED: March 7, 1949, Western District of Oklahoma; libel amended on April 27, 1949.

ALLEGED SHIPMENT: During July 1946 and on or about September 9, 1948, by Dr. Fred Gerkey, from Mission, Kans., via the automobile of Franklin D. Lee; and on or about January 2, 1949, by Dr. Fred Gerkey, from Mission, Kans., via common carrier.

PRODUCT: 4 *Color-Therm devices*, together with 9 applicators, 15 cabinets, and 14 transformers, at Britton, Okla. The devices were accompanied by printed sheets headed "Instructions." The printed sheets were copies which had been prepared by Franklin D. Lee, from an original which had been supplied to him by Dr. Gerkey.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the devices, namely, in the above-mentioned printed sheets, were false and misleading. The statements represented and suggested that the devices were effective in the treatment of any disease condition, and, in particular, disorders of the liver and eyes, female trouble, asthma, nervousness, and sinus trouble. The devices were not effective in the treatment of such disease conditions. The devices were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: Franklin D. Lee, claimant, filed a plea of intervention, alleging that the printed sheets did not constitute labeling of the devices. The case came up for trial before the court on April 27, 1949, and after the introduction of evidence relating to the preparation and shipment of the circulars, the court, upon motion of the claimant, ordered that the libel be dismissed.

An appeal was taken by the Government to the United States Court of Appeals for the Tenth Circuit, and on July 27, 1949, the following opinion was handed down:

PHILLIPS, *Chief Judge:* "This is an appeal from an order dismissing an action to condemn instituted under the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. §§ 301–392, 52 Stat. 1040, as amended by the Act of June 24, 1948, 62 Stat. 582).[1]

"The action was commenced by filing a libel seeking the seizure and condemnation of 4 devices, 9 applicators, 15 cabinets, 14 transformers and certain documents designated as instructions. The information alleged that the articles were devices as defined in 21 U. S. C. A. § 321 (h) and were misbranded within the meaning of 21 U. S. C. A. § 352 (a), while held for sale after shipment in interstate commerce, by reason of false and misleading labeling claims that the devices were effective in the treatment of any disease and, in particular, of disorders of the 'liver, eyes, female trouble, asthma, nervousness and sinus trouble.'

"Each device consists of a wooden cabinet with a series of tubes on top thereof for producing colored lights similar to neon lights, together with electrical connections needed to operate them and an accessory applicator consisting of two tubes, a handle and an extension cord to connect it with the main device. The user is instructed to place his bare feet on the cabinet tubes, elevate his head so that he can see the colors, and to massage with the applicator tubes the area of the body affected.

"Lee, a salesman of the devices, filed a petition in intervention in which he alleged that he was the owner of the seized devices; that they were seized without a search warrant; that the instructions did not physically accompany the devices in interstate commerce, and were not affixed to the devices while in Lee's possession, and that he had not shipped the instructions in interstate commerce.

"The case came on for trial without a jury. Lee and his counsel admitted that the devices and applicators had been transported in interstate commerce into the State of Oklahoma.

"The evidence established that in February, 1949, Lee, at Britton, Oklahoma, gave inspectors of the Food and Drug Administration one copy each of two instructions; that other copies were in Lee's possession; that the copies were typed in Oklahoma from an original instruction circular furnished to Lee by Dr. Fred Gerkey of Mission, Kansas, and were to be used in connection with the sale of the devices; that it was Lee's practice when he made a sale of one of the devices to fold a copy of one of the instructions and place it under the tubes in the device before delivering it to the purchaser.

"Before the United States had an opportunity to introduce medical testimony to establish that the instructions contained false and misleading statements concerning the therapeutic value of the devices, the court held that since the instructions did not move in interstate commerce, there was no false labeling within the meaning of the Act.

"The pertinent provisions of the Act read as follows:

> § 301 (m). The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. [21 U. S. C. A. 321 (m)].
>
> § 304 (a). Any article of . . . device, . . . that is . . . misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce

[1] Hereinafter called the Act.

> . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. . . . [21 U. S. C. A. 334 (a), as amended].
>
> § 502. A drug or device shall be deemed to be misbranded—(*a*) If its labeling is false or misleading in any particular. [21 U. S. C. A. 352 (a)].

"It was not necessary that the instructions be physically attached to the devices. They accompanied such devices within the meaning of § 301 (m), supra. In *Kordel* v. *United States*, 335 U. S. 345, the court said:

> One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant.

"Here, the devices and instructions for the use thereof were in Lee's possession and when a sale was effected the device and instructions were delivered simultaneously.

"The devices were misbranded by Lee while held for sale after shipment in interstate commerce.

"The purpose of the Act is to safeguard the consumer by applying its requirements to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer, and the Act embraces misbranding while held for sale after shipment in interstate commerce.[2]

"In *United States* v. *Sullivan*, 332 U. S. 689, 697, the court held that the Act, so construed, does not exceed the constitutional power of Congress under the commerce clause or invade the powers reserved to the states.[3]

"Lee's contention that review should have been sought by writ of error rather than appeal is without merit. Appeals were substituted for writs of error by the Act of January 31, 1928, 45 Stat. 54.

"The Judgment is REVERSED and the cause REMANDED for further proceedings not inconsistent with this opinion."

Following the remanding of the case to the United States District Court for the Western District of Oklahoma, a motion for summary judgment was made on behalf of the Government.

On April 3, 1950, the court sustained such motion on the ground (1) that the devices and the labeling involved were identical with the devices called Cosmo-Light and their labeling, which were involved in a previous seizure action against the device and a criminal prosecution of Dr. Fred Gerkey (reported in notices of judgment on drugs and devices, Nos. 2388 and 2437); and (2) that the issue of misbranding which was raised in the afore-mentioned cases was decided favorable to the Government and was therefore res judicata. The court, therefore, ordered that the devices and their parts be condemned and that the United States marshal deliver such devices and parts to the Food and Drug Administration.

This judgment was appealed to the United States Court of Appeals for the Tenth Circuit, and on March 12, 1951, the following opinion was handed down by that court:

PHILLIPS, *Chief Judge:* "This is an action to condemn certain devices, instituted under the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040, as amended by the Act of June 24, 1948, 62 Stat. 582, 21 U. S. C. A. §§ 301–392.[1]

"The devices are called 'Color-Therm.' Each consists of a cabinet, a series of tubes mounted thereon which produce colored lights similar to neon lights,

[1] Hereinafter called the Act.
[2] United States v. Sullivan, 332 U. S. 689, 696–697.
[3] See also McDermott v. Wisconsin, 228 U. S. 115, 131.

an applicator attachable to the cabinet by an extension cord and consisting of a handle and two tubes similar to those described above, and electrical accessories and connections for the operation of the device.

"The action was commenced by filing a libel of information. The libel alleged the Color-Therms to be devices as defined in 21 U. S. C. A. § 321 (h) and that they were misbranded within the meaning of 21 U. S. C. A. § 352 (a), while held for sale after shipment in interstate commerce, by reason of false and misleading claims in certain documents designated as instructions,[2] which accompanied the devices, that the devices were effective in the treatment of any disease, and particularly in disorders of the 'liver, eyes, female trouble, asthma, nervousness and sinus trouble.'

"Lee, a salesman of the devices, filed a petition in intervention in which he alleged that the instructions seized with the devices did not physically accompany the devices in interstate commerce and were not affixed to or connected with the devices while they were in his possession; that prior to the seizure of the devices the use of such instructions had been abandoned and new and appropriate circulars had been substituted therefor; and that he had not shipped the instructions in interstate commerce. He did not deny that the representations made in the instructions were false and misleading, or that, prior to such alleged abandonment, the instructions had accompanied the seized devices while they were held by him for sale after shipment thereof in interstate commerce.

"An investigation of the devices and instructions was made by agents of the Food and Drug Administration on February 7 and 8, 1949. The seizure took place shortly after March 7, 1949.

"The case came on for hearing and Lee admitted that the devices had been shipped in interstate commerce and were held for sale by him after such shipment, and that assembled devices were kept and displayed for sale at his place of business, which was a room in his house, and that he also kept in such room copies of the instructions. One of the instructions was introduced in evidence. Lee admitted its authenticity. The instructions direct the user to place his bare feet on the cabinet tubes, position his head so that he can see the colors, and massage with the applicator tubes the area of the body he desires to treat. The evidence established that on February 7, 1949, Lee, at Britton, Oklahoma, gave inspectors of the Food and Drug Administration one copy of the instructions; that other copies were in Lee's possession; that the copies were typed in Oklahoma from an original instruction circular furnished to Lee by Fred Gerkey of Mission, Kansas, and were used by Lee in connection with the sale of the devices; that it was Lee's practice when he made a sale of one of the devices to fold one of the instructions and place it under the tube of the device before delivering it to the purchaser. When it appeared that the challenged instructions had not moved in interstate commerce, the trial court held that there was no false labeling within the meaning of the Act and dismissed the proceeding. On appeal we reversed. See United States v. Four Devices, 10 Cir., 176 F. 2d 652. We held that it was not necessary that the instructions be physically attached to the devices; that the instructions accompanied the devices within the meaning of § 301 (1), supra, if they supplemented or explained the devices, and that in such a situation textual relationship, rather than physical attachment is the significant fact.[3] We further held that the Act embraces the misbranding of a device while held for sale after shipment in interstate commerce.

"On remand the trial court sustained a motion of the United States for summary judgment. In support of the motion, in addition to the pleadings in the proceeding, the United States submitted: a certified copy of a libel of information filed in the United States District Court for the Southern District of California, Central Division, and thereafter transferred to the Western District of Missouri, against a like device; answer of Fred Gerkey filed therein; and the judgment entered in that cause adjudging the devices misbranded by a set of instructions substantially identical with those involved in the instant action and ordering condemnation of the devices and instructions; and an affidavit made by Lee on February 8, 1949. The affidavit averred: that Lee was the Oklahoma distributor for Fred Gerkey, who makes the devices; that

[2] Hereinafter called instructions.
[3] See Kordel v. United States, 335 U. S. 345, 350.

he acted upon Gerkey's instructions; that the instructions were brought to Oklahoma City by Gerkey on or about July 15, 1948; that he had additional copies of the instructions typewritten, and that the devices or the unassembled parts thereof were shipped to him in Oklahoma from points outside the State of Oklahoma. Lee admitted that the instructions were false and misleading.

"From the foregoing, other than the evidence introduced at the original hearing, the following facts were established without contradiction and no issue existed with respect thereto, namely: The devices had been shipped in interstate commerce and were thereafter held for sale by Lee; the original set of instructions were transported in interstate commerce; from those original instructions typewritten copies were made; the instructions were false and misleading; copies of the instructions were kept by Lee in his place of business, which was a room in his house, where the assembled devices were kept and displayed for sale; the instructions explained the devices, directed the manner of using them to cure disease and were textually related to the devices; prior to the seizure and while the devices were held for sale after shipment in interstate commerce, the false and misleading instructions accompanied the devices; Gerkey was the owner of the devices; and Lee acted as the agent of Gerkey and followed Gerkey's instructions.

"Therefore, if any issue of fact remained, it arose because of the allegation by Lee in his intervention that sometime before the seizure Lee had abandoned the use of the false and misleading instructions.

"Section 334 (a), supra, provides that any device that is 'misbranded when introduced into or while in interstate commerce or while held for sale * * * after shipment in interstate commerce, * * * shall be liable to be proceeded against while in interstate commerce, *or at any time thereafter*, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found.' [Italics added.]

"Once a device is misbranded when introduced into or while in interstate commerce, or while held for sale after shipment in interstate commerce, it is subject to seizure at any time, and the fact that at the time of seizure, the false label is not upon the device or does not accompany the device does not purge the device of its prior false labeling or render it immune from seizure and condemnation.[4]"

3458. Misbranding of violet ray device. U. S. v. 2 Cases * * *. (F. D. C. No. 30801. Sample No. 3858-L.)

LIBEL FILED: Between March 2 and April 24, 1951, District of Maryland.

ALLEGED SHIPMENT: On or about July 24, 1950, by Master Appliances, Inc., from Marion, Ind.

PRODUCT: 2 imitation leather cases, each containing a violet ray device, a general electrode, a rake electrode, a throat electrode, and circulars entitled "The Master High Frequency Violet Ray," "The Master High Frequency Violet Ray A Professional Aid to Health and Beauty," and "Directions For Operating," at Baltimore, Md.

Examinations showed that the product consisted essentially of Geissler tubes of various shapes with a transformer assembly to activate them, designed to apply an intermittent ray discharge to the body.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading. The statements represented and suggested that the device would produce pleasing, invigorating, and corrective effects; that it would be effective as a general treatment by stimulating the circulation; that it would be effective for beauty, health, and strength; that it would be efficacious in the treatment of rheumatic pain in the shoulder,

[4] United States v. Various Quantities of Articles of Drug, D. C. 83 F. Supp. 882, 887; United States v. 1 Dozen Bottles, etc., 4 Cir., 146 F. 2d 361, 363. See also, United States v. Olsen, 9 Cir., 161 F. 2d 669, 671; United States v. 52 Drums Maple Syrup, 2 Cir., 110 F. 2d 914, 915; United States v. Two Bags, etc., 6 Cir., 147 F. 2d 123, 128.